DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 3 2003

APR 3 1 2003

Re: Zevalin
Docket No.: 02E-0343

The Honorable James E. Rogan
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Box Pat. Ext.
P.O. Box 2327
Arlington, VA 22202

Dear Director Rogan:

This is in regard to the application for patent term extension for U.S. Patent No. 5,776,456, filed by IDEC Pharmaceuticals Corporation, under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for Zevalin, the human biological product claimed by the patent.

The total length of the regulatory review period for Zevalin is 3,363 days. Of this time, 2,887 days occurred during the testing phase and 476 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this biologic product became effective: December 7, 1992.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on December 7, 1992.

2. The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act: November 1, 2000.

   FDA has verified the applicant's claim that the product license application (BLA) for Zevalin (BLA 1250190) was initially submitted on November 1, 2000.

3. The date the application was approved: February 19, 2002.

   FDA has verified the applicant's claim that BLA 1250190 was approved on February 19, 2002.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Robin L. Teskin
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